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21 *Attorneys for Defendant Hill's Pet Nutrition, Inc.*

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

HEMOPET,

Plaintiff,

v.

HILL'S PET NUTRITION, INC.

Defendant.

JURY TRIAL DEMANDED

Case No. SACV 12-01908-(JLS-JPRx)
Action Filed: November 2, 2012

**HILL'S NOTICE OF MOTION FOR
SUMMARY JUDGMENT OF PATENT
INVALIDITY UNDER 35 U.S.C. §§ 101,
102 AND NON-INFRINGEMENT**

DATE: November 14, 2014
TIME: 2:30 p.m.
COURTROOM: 10-A
JUDGE: The Honorable Josephine Staton

1 TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

2 PLEASE TAKE NOTICE that on November 14, 2014 at 2:30 p.m., or as soon
3 thereafter as the matter may be heard, before the Honorable Josephine Staton, United
4 States District Judge, District Court for the Central District of California, Southern
5 Division, 411 West Fourth Street, Courtroom 10-A, Santa Ana, CA 92701, Defendant
6 Hill's Pet Nutrition, Inc. ("Hill's") will present its motion for summary judgment of
7 patent invalidity under 35 U.S.C. §§ 101, 102 and non-infringement. This motion is
8 made following the conference of counsel that took place pursuant to L.R. 7-3 on
9 September 11, 2014.

10 Respectfully submitted,

11 DATED: September 18, 2014 KIRKLAND & ELLIS LLP

12 /s/ Bryan S. Hales

13 Bryan S. Hales, P.C.

14 *Attorneys for Defendant*
15 *Hill's Pet Nutrition, Inc.*

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CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2014, I electronically filed the foregoing document with the Clerk of Court using CM/ECF, which sent notification of such filing to all counsel of record.

/s/ *Bryan S. Hales*

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102 AND NON-INFRINGEMENT**

DATE: November 14, 2014

TIME: 2:30 p.m.

COURTROOM: 10-A

JUDGE: The Honorable Josephine Staton

1 Hill's Pet Nutrition, Inc. ("Hill's") requests this Court grant its motion for
2 summary judgment of patent invalidity under 35 U.S.C. §§ 101, 102, and non-
3 infringement. Specifically, Hill's moves pursuant to Fed. R. Civ. P. 56(a) for the
4 following:

- 5 1. Claims 1 and 2 of U.S. Patent No. 7,865,343, claims 1, 2, 9, and 10 of U.S.
6 Patent No. 8,060,354, claim 1 of U.S. Patent 8,234,099, and claims 1 and 8 of
7 U.S. Patent No. 8,224,587 are invalid under 35 U.S.C. § 101;
- 8 2. Claims 1, 2, 9, and 10 of U.S. Patent No. 8,060,354, claim 1 of U.S. Patent
9 8,234,099, and claims 1 and 8 of U.S. Patent No. 8,224,587 are invalid under 35
10 U.S.C. § 102;
- 11 3. Claims 1 and 2 of U.S. Patent No. 7,865,343, claims 1, 2, 9, and 10 of U.S.
12 Patent No. 8,060,354, claim 1 of U.S. Patent 8,234,099, and claims 1 and 8 of
13 U.S. Patent No. 8,224,587 are not infringed;
- 14 4. Hill's acts of using, selling, or offering for sale pet food products do not
15 infringe claims 1 or 2 of U.S. Patent No. 7,865,343, claims 1, 2, 9, or 10 of U.S.
16 Patent No. 8,060,354, claim 1 of U.S. Patent 8,234,099, or claims 1 or 8 of U.S.
17 Patent No. 8,224,587;
- 18 5. The process that Hill's uses to manufacture pet food products does not infringe
19 claims 1 or 2 of U.S. Patent No. 7,865,343, claims 1, 2, 9, or 10 of U.S. Patent
20 No. 8,060,354, claim 1 of U.S. Patent 8,234,099, or claims 1 or 8 of U.S. Patent
21 No. 8,224,587; and
- 22 6. Hill's identification of any ingredients prior to the issuance of the Asserted
23 Patents does not infringe claims 1 or 2 of U.S. Patent No. 7,865,343, claims 1, 2,
24 9, or 10 of U.S. Patent No. 8,060,354, claim 1 of U.S. Patent 8,234,099, or
25 claims 1 or 8 of U.S. Patent No. 8,224,587.

26 This motion is based on the Notice of Motion and Motion, the concurrently-
27 filed memorandum in support of the motion, the concurrently-filed declaration of
28

1 Bryan S. Hales and the exhibits thereto, the concurrently-filed declaration of Dr. Jean
2 Hall in support and the exhibits thereto, the concurrently-filed statement of
3 uncontested facts and conclusions of law, and the complete files and records in this
4 action, and such other evidence and argument as the Court may consider.

5 Respectfully submitted,

6 DATED: September 18, 2014

7 KIRKLAND & ELLIS LLP

8 /s/ Bryan S. Hales

9 Bryan S. Hales, P.C.

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HEMOPET,

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HILL'S PET NUTRITION, INC.

Defendant.

Case No. SACV 12-01908-(JLS-JPRx)

**HILL'S MEMORANDUM IN SUPPORT
OF ITS MOTION FOR SUMMARY
JUDGMENT OF PATENT
INVALIDITY UNDER 35 U.S.C. §§ 101,
102 AND NON-INFRINGEMENT**

DATE: November 14, 2014

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JURY TRIAL DEMANDED

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 2 496 Fed. Appx. 65 (Fed. Cir. 2012) 8, 10, 11, 12

3 *Planet Bingo, LLC v. VKGS LLC*,
 4 No. 2013-1663,
 5 2014 WL 4195188 (Fed. Cir. 2014, Aug. 26, 2014) 15

6 *Schering Corp. v. Geneva Pharmaceuticals*,
 7 339 F.3d 1373 (Fed. Cir. 2003) 17, 19

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 11 54 F.3d 1570 (Fed. Cir. 1995) 20

12 *T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n*,
 13 809 F.2d 626 (9th Cir. 1987) 6

14 *Telemac Cellular Corp. v. Topp Telecom, Inc.*,
 15 247 F.3d 1316 (Fed. Cir. 2001) 16

16 **STATUTES**

17 35 U.S.C. §§ 101 2, 7, 14, 25

18 35 U.S.C. §§ 102 2, 25

19 35 U.S.C. §§ 102(b) 16

20 **OTHER AUTHORITIES**

21 Biological Science, 5th Edition at 258 20

22 **RULES**

23 Fed. R. Civ. P. 56(a) 2

24 Fed. R. Civ. P. 56(c) 6

INTRODUCTION

The named inventor of Hemopet’s Asserted Patents in this case has stated that “I have secured the pioneer patents for nutrigenomics pet foods dating back to 1999....As a result, I am effectively *the gatekeeper to a concept....*” (Ex. 13, HEMOPET0005705) (emphasis added).¹ But the law does not allow patents on concepts. Nor does it allow patents that could be a “gatekeeper” to a field by purporting to cover any way of implementing abstract ideas. Yet, the Asserted Claims attempt just that; they combine elements directed to naturally occurring phenomena (unpatentable) with abstract elements (unpatentable), which cannot be saved by the addition of a generic computer (unpatentable). Recent Supreme Court and Federal Circuit decisions—issued after the U.S. Patent Office (PTO) examined the Asserted Patents—have advanced the law regarding unpatentable subject matter and leave no doubt that the Asserted Claims are invalid. Hemopet’s expert suggests that because the Asserted Claims involve highly complex and voluminous data, it somehow transforms patent ineligible subject matter into protectable inventive concepts. But this view contradicts what Hemopet told the PTO during prosecution to overcome rejections, namely that “data is data” even if complex and of a large scale. The fact is that nothing in the claim language goes beyond generic, abstract concepts.

Such contradictions pervade Hemopet’s positions in this case. On the issue of anticipation, Hemopet concedes that the PCT Ghai prior art reference—which the PTO did not consider when it examined the Asserted Patents—discloses all elements of the Asserted Claims of three of the four Asserted Patents, except the presence or use of a computer. Hemopet argues that a computer is not inherently disclosed by PCT Ghai, even though PCT Ghai discloses the use of microarrays, a high throughput

1 Unless noted otherwise, exhibit numbers correspond to the Exhibits attached
to the Declaration of Bryan S. Hales, filed concurrently with this motion for
summary judgment and Hill's statement of uncontested facts and
conclusions of law.

1 research tool. That position directly contradicts Hemopet's own expert, Dr. Sutter,
 2 who admitted that using a microarray *necessarily* requires the use of a computer to
 3 handle the large volume of data, which meets the standard for inherency.

4 Regarding infringement, it is axiomatic that a patentee can be his or her own
 5 lexicographer and give whatever meaning he or she wishes to the terms in the patent.
 6 But because the public relies on what is said in the patent, the patentee must live with
 7 his or her prescribed meaning, even if it results in non-infringement. During claim
 8 construction, Hemopet proposed a construction for "expression of" that contained the
 9 term "gene product." The Court adopted Hemopet's proposal. But Hemopet gave
 10 that term, "gene product," an expressly defined meaning in the specification, that it
 11 must include "phenotypic" information. Thus, to satisfy the "expression of" element
 12 as proposed by Hemopet in the claimed "second data" and construed by the Court,
 13 Hill's activities accused of satisfying the "second data" element must have *phenotypic*
 14 information. They do not, as they only have messenger RNA ("mRNA") expression
 15 data, which is *genotypic* information. Unable to dispute what Hill's activities are,
 16 Hemopet seeks to avoid the consequences of its express definition and adopted claim
 17 construction through its expert's new argument that mRNA expression data is
 18 phenotypic. That position is not supported by the specification and directly opposes
 19 statements made by its expert, Dr. Sutter, earlier in the case, namely that mRNA
 20 expression data is related to "*genotype* as contemplated by the patent." (Ex. 6, 6/19/14
 21 Sutter at ¶ 83).

22 The Court should grant summary judgment of invalidity for lack of patentable
 23 subject matter, invalidity by anticipation, and non-infringement. In addition, Hill's
 24 seeks partial summary judgment on three non-infringement issues that should not be
 25 controversial, but to which Hemopet would not stipulate: (1) that Hill's use and sale
 26 of pet food does not infringe, (2) that Hill's process of manufacturing physical pet
 27 food kibble does not infringe, and (3) that Hill's work to identify key ingredients

1 before the Asserted Patents issued does not infringe. These points are plain from the
 2 claim language and governing law, yet Hemopet refuses to agree, apparently because
 3 of the way it seeks to use non-infringing activity to support its damages calculation
 4 methodology. Whether the law supports Hemopet's damages methodology is for
 5 another day, but to avoid jury confusion and streamline the issues for trial, the Court
 6 should grant partial summary judgment of non-infringement on these points as well.

7 **BACKGROUND**

8 **I. THE NATURE OF THE PROCEEDINGS**

9 Hemopet accuses Hill's Rational Diet Design program ("RDD") of infringing
 10 U.S. Patent 7,865,343 ("the '343 Patent"), U.S. Patent 8,060,354 ("the '354 Patent"),
 11 U.S. Patent 8,234,099 ("the '099 Patent"), and U.S. Patent 8,224,587 ("the '587
 12 Patent") (together, "the Asserted Patents"). (D.I. 19; *see also* Exs. 1-4). The Court
 13 issued its claim construction order on May 13, 2014 construing a number of claim
 14 terms. (D.I. 76). Trial is scheduled to begin January 27, 2015. (D.I. 85).

15 Hemopet asserts claims 1 and 2 of the '343 Patent, claims 1, 2, 9, and 10 of the
 16 '354 Patent, claim 1 of the '099 Patent, and claims 1 and 8 of the '587 Patent
 17 (together, "the Asserted Claims"). (D.I. 87-1 at Page ID 1846-47). The Asserted
 18 Claims are directed to comparing a "first data" to a "second data" and, based on the
 19 comparison, determining or preparing a nutrient or caloric composition for a canine or
 20 feline. Both the "first" and "second" data occur in nature. The "first data" is genomic
 21 data that corresponds to a physiological condition, and the "second data" is data
 22 relating to the effect of nutrients on the genomic data. (*See* Exs. 1-4). Determining
 23 and preparing a nutrient or caloric composition, without more specificity, is an
 24 abstract idea under the law.

25 **II. THE PRIOR ART DISCLOSES THE CLAIMED INVENTIONS**

26 International patent application PCT WO 97/48823 to Ghai et al. ("PCT Ghai"),
 27 titled Methods of Screening Foods for Nutraceuticals, is remarkably similar to the
 28

1 Asserted Claims. Notably, although PCT Ghai is undisputedly prior art, the PTO did
 2 not consider PCT Ghai when it examined and issued the Asserted Patents.

3 The chart below shows exemplary Asserted Claim limitations on the left and
 4 PCT Ghai disclosures on the right, which essentially overlap one another. Not
 5 surprisingly, Hemopet does not dispute that PCT Ghai discloses the claim limitations
 6 on the left. (Ex. 7, 7/17/14 Sutter Report at ¶¶150-154). As discussed below,
 7 Hemopet only disputes whether PCT Ghai discloses the claimed computer, computer
 8 software and database to carry out these limitations.

Claim Limitations	Exemplary PCT Ghai Disclosures
“first data relating the expression of at least one gene to a physiological condition...”	“[a]ny gene or functional nucleotide sequence, including any expressed sequence tag (EST)...associated with or related to the development, onset, progression or other manifestation of any disease...in human or other animal” (Ex. 5 at 12:34-37).
“second data compromising the effect of nutrition on the expression of at least one gene of the genomic map”	data relating to “the effect of exposure to a food or food substance on the expression of disease-related gene(s) in cells” (<i>Id.</i> at 4:32-33).
“determining a relationship between the first and second data”	“ability of the food or food substance to modulate expression of a disease-related gene in an animal model” (<i>Id.</i> at 5:1-2).
“preparing a nutritional diet product”	“invention provides compositions comprising one or more nutraceuticals identified according to the method[s]” (<i>Id.</i> at 5:6-8).

24 III. HILL’S ACCUSED RATIONAL DIET DESIGN PROGRAM

25 RDD is a Hill’s internal software program research tool that produces data
 26 showing the effect of potential food ingredients on gene expression in animals. (Ex.
 27 10, K. Hahn Dep. at 15:6-22, 17:1-6, 33:18-25; *see also* Ex. 7, 6/19/14 Sutter Report

1 at ¶65). RDD contains gene expression data from tissue studies and ingredient cell
 2 culture studies, and identifies the effect, if any, of potential food ingredients on gene
 3 expression profiles of animals. (Ex. 8, S. Malladi Dep. at 49:12-15, Ex. 9, D. Jewell
 4 Dep. at 25:11-26:6). Gene expression as measured by messenger RNA levels is the
 5 only response measured and collected during the ingredient cell culture and tissue
 6 studies. (Ex. 9, Jewell Dep. at 25:9-18, 28:1-23; 31:15-20, 33:25-34:2; Ex. 8, S.
 7 Malladi Dep. at 20:7-21:3; Ex. B to Hall Decl.² at ¶¶65-67, 73-74, 77). The output of
 8 RDD is a list of ingredients and the number of genes that were expressed in a
 9 favorable direction and the number of genes expressed in an unfavorable direction.
 10 (Ex. 6, 6/19/14 Sutter Report at ¶69).

11 Separate from RDD, Hill's also conducts feeding studies in which it feeds
 12 prototype diets to dogs and cats, and measures the gene expression profiles of the
 13 animals. (Ex. 9, D. Jewell Dep. at 60:16-62:1, 62:21-63:10). The gene expression
 14 measurements consist of messenger RNA levels taken from the animals. (*Id.* at 61:4-
 15 62:1, 62:21-63:10; Ex. B to Hall Decl. at ¶¶98-100).

16 In 2009, approximately two years before issuance of the first Asserted Patent,
 17 Hill's used RDD to identify three key ingredients—tomato pomace, carrot powder,
 18 and coconut oil—used in Hill's Metabolic pet food product. (Ex. 10, K. Hahn Dep. at
 19 97:1-9, 96:17-22, 106:4-21). Hill's identification of the three key ingredients
 20 established the Global Nutritional Standard for Metabolic, Hill's Science Diet Perfect
 21 Weight, Ideal Balance Slim & Healthy, Science Plan VetEssentials Neutered Dog, and
 22 the proposed multisystem pet food. (Ex. 10, K. Hahn Dep. at 97:1-9, 96:17-22, 106:4-
 23 21).

24
 25
 26 2 Citations to “Ex. __, Hall Decl.” refer to exhibits attached to the Declaration of
 27 Dr. Jean Hall, filed concurrently with Hill's motion for summary judgment and
 28 this statement of uncontested facts and conclusions of law.

ARGUMENT

J. LEGAL STANDARD FOR SUMMARY JUDGMENT

Summary judgment is appropriate when “there is no genuine issue as to any material fact” and “the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). A party seeking summary judgment can establish the absence of a genuine issue of material fact in two ways: (1) by presenting evidence that negates an essential element of the nonmoving party’s case; or (2) by demonstrating that the nonmoving party failed to establish an essential element of their case on which they bear the burden of proof at trial. *See Multimedia Patent Trust v. LG Elecs., Inc.*, No. 12-cv-2731-H (KSC), 2013 WL 5779645, at *6 (S.D. Cal. Aug. 1, 2013) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986)). “Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment.” *T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass’n*, 809 F.2d 626, 630 (9th Cir. 1987). The nonmoving party cannot oppose a properly supported summary judgment motion by “rest[ing] on mere allegations.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 259 (1986). And “[t]he ‘opponent must do more than simply show that there is some metaphysical doubt as to the material fact.’” *Kennedy v. Allied Mut. Ins. Co.*, 952 F.2d 262, 265–66 (9th Cir. 1991) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)).

II. THE ASSERTED CLAIMS ARE INVALID UNDER 35 U.S.C. § 101 FOR CLAIMING INELIGIBLE SUBJECT MATTER

The Asserted Claims cover a method of determining a recipe for dog or cat food using two sets of data and a generic computer. The two sets of data reflect naturally occurring phenomena, nothing that Hemopet invented. And the way they are used is abstract, and seek to claim patent ownership of the mere use of a computer to perform conventional steps. Under the law, the Asserted Claims are not patentable.

A. Summary Judgment Under 35 U.S.C. § 101 Is Appropriate

The question of whether a claim is directed to statutory subject matter is a question of law. *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1333 (Fed. Cir. 2010). Although invalidity must be shown by clear and convincing evidence, patent ineligibility is a threshold issue that the Supreme Court has advanced significantly since the Asserted Patents issued. *See e.g., Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014); *see also Eclipse IP LLC v. McKinley Equipment Corp.*, No. CV 14-154-GW(AJWx), 2014 WL 4407592, *4 (C.D. Cal. Sept. 4, 2014) ("[T]he Supreme Court has spoken, and § 101 now plays an important limiting role.").

B. Abstract Ideas and Laws of Nature Are Not Patentable Subject Matter Under 35 U.S.C. § 101

“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, [because] they are the basic tools of scientific and technological work”. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1293 (2012) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). In its recent *Alice* decision, the Supreme Court affirmed the framework to be used in order to distinguish ineligible patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, courts must “determine whether the claims at issue are directed to patent-ineligible concepts.” *Alice*, 134 S.Ct. at 2355 (citations omitted). If the claims are directed to patent-ineligible concepts, courts must “consider the elements of each claim both individually and ‘as an ordered combination’ to determine whether additional elements ‘transform the nature of the claim’ into a patent-eligible application.” *Id.*

C. The Asserted Claims Are Directed To Ineligible Concepts

The first step of the section 101 analysis requires examination of the Asserted Claims to determine if they are directed to patent-ineligible concepts. The Asserted Claims are directed to the abstract concept of determining a nutritional diet for a

1 canine or feline based on naturally occurring relationships between physiological
 2 conditions and genomic data and the effect of nutrition on genomic data. Similar
 3 concepts have repeatedly been rejected as directed towards patent-ineligible subject
 4 matter.

5 In *Mayo*, the Supreme Court found claims for a method for measuring
 6 metabolites in the bloodstream in order to calibrate the appropriate dosage of
 7 thiopurine drugs in the treatment of autoimmune diseases to be directed to patent-
 8 ineligible concepts. *Mayo*, 132 S.Ct., at 1296-1297. In *PerkinElmer*, the claims
 9 covered a multi-step method of: (1) measuring the levels of certain biological markers
 10 from both the first and second trimester of pregnancy; and (2) determining whether an
 11 increased risk of Down's syndrome existed by comparing those markers.
PerkinElmer, Inc. v. Intema Ltd., 496 Fed. Appx. 65, 70-71 (Fed. Cir. 2012). The
 12 Federal Circuit concluded that the claims contained a patent-ineligible law of nature
 13 and specifically that “the relationship between screening marker levels and the risk of
 14 fetal Down's syndrome” is a “natural process, an eternal truth that ‘exists in principle
 15 apart from any human action.’” *Id.* at 70 (quoting *Mayo*, 132 S.Ct. at 1297.) In
 16 *Genetic*, the claims were directed to a correlation between a particular genetic
 17 variation and sprinting, strength or power performance. *Genetic Technologies Limited*
 18 v. *Lab. Corp. of America Holdings*, CV 12-1736-LPS-CJB, 2014 WL 4379587, *10
 19 (D. Del. Sept. 3, 2014). The District of Delaware in *Genetic* found that “the link
 20 between a particular genetic variation and the potential for elite athletic performance”
 21 is directed to a patent-ineligible concept. *Id.*

22 The Asserted Claims in the present case are directed to patent-ineligible
 23 concepts under these principles. They are directed to the abstract concept of applying
 24 naturally occurring relationships between physiological conditions and genomic data
 25 and the effect of nutrition on genomic data when determining a nutritional diet for a
 26 canine or feline. *See Mayo*, 132 S.Ct. at 1296-97 (rejecting the concept of reciting a
 27

1 law of nature followed by an “apply the law” step).

2 **D. The Asserted Claims Contain No Inventive Concept**

3 The second step in a Section 101 analysis requires an examination of “the
 4 elements of the claim to determine whether it contains an inventive concept sufficient
 5 to transform the claimed abstract idea into a patent-eligible application.” *Alice*, 134
 6 S.Ct. at 2357 (citations omitted). Courts examining this question should look first to
 7 each step of the claim, and then to the claim as a whole. *Id.* at 2355. The Asserted
 8 Claims fail on both fronts. Claim 2 of the ‘354 patent is representative:

9 2. A system for determining a nutritional diet for a canine or feline
 10 companion animal comprising: a computer; at least one electronic
 11 database coupled to the computing system; at least one software routine
 12 executing on the computing system which is programmed to:

13 (a) receive first data relating the expression of at least one gene to a
 14 physiological condition; wherein the data relating to the expression of the
 15 at least one gene includes genomic map data; and the genomic map data
 16 concerns the physiological condition of the animal;

17 (b) receive second data comprising the effect of nutrition on the
 18 expression of at least one gene of the genomic map;

19 (c) determine a relationship between the first and second data; and

20 (d) determine nutritional content based on the relationship; and formulate
 21 a nutritional diet product for the canine or feline companion animal.

(Ex. 2 at claim 2).

22 As will be discussed, steps (a) and (b) describe naturally occurring phenomena,
 23 while steps (c) and (d) recite an abstract idea, with no detail or explanation of how to
 24 determine the relationship, determine the content or formulate the diet.

1. Each step of the claims is directed to ineligible subject matter

2 a. Steps (a) and (b) reflect unpatentable natural
3 phenomena

4 The first and second steps are directed to receiving two sets of data. The
 5 claimed first data is data relating the expression of genes to a physiological condition.
 6 The claimed second data is data relating to the effect of nutrition on the expression of
 7 genes. These claimed relationships are not patent eligible because they are naturally
 8 occurring. *See e.g., Mayo*, 132 S.Ct. at 1297; *PerkinElmer*, 496 Fed. Appx. at 70; *see also Genetic*, 2014 WL 4379587 at *10 (noting that the claimed “correlation is the
 9 handiwork of nature—man did not do anything to bring about this relationship”).

10 In *Mayo*, the claims recited relationships between concentrations of certain
 11 metabolites in the blood and the likelihood that a dosage of a thiopurine drug would
 12 prove ineffective or cause harm. *Mayo*, 132 S.Ct. at 1296. This relationship is a law
 13 of nature, the Supreme Court explained, because it “exists in principle apart from any
 14 human action.” *Id.* at 1297. It did not matter to the Court that a human action
 15 (administration of the drug) was required to trigger a manifestation of the relationship,
 16 because the relation itself is an “entirely natural process[]”—a result of the way in
 17 which the body metabolizes thiopurine compounds. *Id.*

18 Similarly, in *PerkinElmer*, the claims recited “the relationship between
 19 screening marker levels and the risk of fetal Down’s syndrome.” *PerkinElmer*, 496
 20 Fed. Appx. at 70 (Fed. Cir. 2012). The Federal Circuit found that the relationship is a
 21 “natural process, an eternal truth that ‘exists in principle apart from any human
 22 action.’” *Id.* (citation omitted). And likewise, the District of Delaware recently held
 23 “the link between a particular genetic variation and the potential for elite athletic
 24 performance [to be] a ‘natural process, an eternal truth that exists in principle apart
 25 from human action.’” *Genetic*, 2014 WL 4379587 at *10. Indeed, the Supreme Court
 26 last year made clear that even discovering a groundbreaking genetic relationship—a
 27 gene associated with increased risk for breast cancer—was unpatentable because it
 28

was a product of nature. *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2117 (2013).

The first data and second data elements of the Asserted Claims are naturally occurring like the elements in *Mayo*, *Myriad*, *PerkinElmer* and *Genetic*. The genes associated with a particular condition are a product of nature, as is the expression of those genes. Likewise, the effect a nutrient has on the expression of a gene is a product of nature. Observing, receiving or recording those relationships is not the product of human ingenuity. Indeed, Hemopet conceded it “didn’t discover the molecular relationships between nutrition and the responsive genes in promoting health.” (Ex. 11, J. Dodds Dep. at 164:23-165:2; *see also* 143:11-15 (admitting that “it was known before [Dr. Dodds] did [her] work in 1999, that particular foods or substances could up- or down-regulate gene expression); *see also id.* at 166:8-12 (admitting that Dr. Dodds wasn’t “the first person to disclose ... the five basic concepts of nutrigenomics”)). Likewise, storing information about this natural relationship in a database (electronic or otherwise) does not transform the information to make it patent eligible. *Alice*, 134 S.Ct. at 2359 (rejecting “the use of a computer to obtain data” or to perform “electronic record keeping” as eligible subject matter because they are “basic functions of a computer”). The claimed relationships in the first and second data are no different than the claimed relationships rejected in *Mayo*, *PerkinElmer*, and *Genetic*.

b. Steps (c) and (d) are unpatentable abstract ideas

Step (c) is directed to determining a relationship between the first and second data and step (d) is directed to determining and formulating a nutritional diet (*i.e.*, a particular nutrient or caloric composition) based on the relationship in step (c). Recent cases from the Supreme Court and Federal Circuit make clear these elements are abstract ideas that are not patentable. *Mayo*, 132 S.Ct. at 1302 (rejecting a “determining” step); *PerkinElmer*, 496 Fed. Appx. at 71 (same); *Genetic*, 2014 WL

1 4379587 at *11-13 (rejecting an “analyzing” and “predicting” step).

2 In *Mayo*, the Court rejected a “determining” step because it was “set forth in
 3 highly general language covering all processes that make use of the correlations after
 4 measuring metabolites....” *Mayo*, 132 S.Ct. at 1302. Elements (c) and (d) are
 5 analogous. The elements “determine a relationship,” “determine nutritional content,”
 6 and “formulate a diet product” are highly general and purport to cover any way of
 7 making use of the naturally occurring correlations of (a) and (b), just as in *Mayo*.

8 Similarly, in *PerkinElmer*, the Federal Circuit found that the “determining” step
 9 recited the “ineligible mental step of ‘comparing the measured markers with observed
 10 relative frequency distributions of marker levels in Down’s syndrome pregnancies and
 11 in unaffected pregnancies’ to determine the risk of fetal Down’s syndrome.””
 12 *PerkinElmer*, 496 Fed. Appx. at 71. And in *Genetic*, the court found ineligible an
 13 “analyzing” step because it “essentially tells the user to analyze the sample through
 14 whatever known processes they wish to use.” *Genetic*, 2014 WL 4379587 at *11.

15 As in *PerkinElmer* and *Genetic*, and like *Mayo* above, the elements here are
 16 claimed in “highly general language covering all processes that make use of the
 17 correlations” found between the first and second data. *Mayo*, 132 S.Ct. at 1302.
 18 Indeed, neither the patent claims nor the specification provide any detail whatsoever
 19 regarding how these steps are to be performed.

20 **2. The Asserted Claims as a whole are directed to unpatentable
 21 subject matter**

22 The Asserted Claims as a whole do not transform the ineligible claim elements
 23 into a patent-eligible inventive concept. *See e.g.*, *Alice*, 134 S.Ct. at 2355. Instead,
 24 like the claims in *Mayo*, the claimed “combination amounts to nothing more than an
 25 instruction to doctors to apply the applicable laws when treating their patients.””
 26 *Mayo*, 132 S.Ct. at 1298.

27 In *Mayo*, the claims covered processes that helped doctors treating patients with

1 autoimmune diseases determine whether a given dosage level is too low or too high
 2 using relationships between the concentration in the blood of certain metabolites and
 3 the likelihood that the drug dosage will be ineffective or introduce harmful side-
 4 effects. *Id.* at 1294. Here, the claims purportedly help one of ordinary skill in the art
 5 determine a nutritional diet for an animal having a physiological condition using the
 6 relationships between gene expression data and the effect of nutrition on the
 7 expression of genes associated with the physiological condition.

8 As in *Mayo*, the first three steps of the Asserted Claims “simply tell doctors to
 9 gather data from which they may draw an inference in light of the correlations.” *Id.* at
 10 1298. The final determining, formulating or preparing a particular nutrient or caloric
 11 composition step based on the data is not “sufficient to transform unpatentable natural
 12 correlations into patentable applications of those regularities.” *Id.* “[S]imply
 13 appending conventional steps, specified at a high level of generality, to laws of nature,
 14 natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas
 15 patentable.” *Id.* at 1300.

16 Hemopet cannot dispute that the determination of a particular nutrient or caloric
 17 composition based on the claimed data is a conventional step in the art. During
 18 prosecution, Hemopet faced a lack of enablement rejection where the PTO alleged
 19 that the pending claims contained “subject matter which was not described in the
 20 specification in such a way as to enable one of ordinary skill in the art to...use the
 21 invention.” (Ex. 15, ‘343 Pros. History, 2/23/10 Rejection at 8). In response,
 22 Hemopet submitted the declaration of Dr. Giger in an attempt to explain why no
 23 undue experimentation is required to practice the claims. (Ex. 16, ‘343 Pros. History,
 24 4/13/10 Amendment at 19).

25 Dr. Giger declared that the claimed technology “is concerned with analyzing,
 26 selecting, designing and development of nutrition based on the effects of nutritional
 27 data with a data base of genetic parameters. ***This analysis, selection, design and***

1 *development is not complex, once the datasets are processed, which would likely*
 2 *have been quite straightforward for data analysts.”* (Ex. 18, 4/12/12 Giger Decl. at ¶
 3 14) (emphasis added). This is exactly the type of post-solution conventional step that
 4 the Court in *Mayo* held does not transform laws of nature, natural phenomena, and
 5 abstract ideas into patent eligible subject matter. *Mayo*, 132 S.Ct. at 1300.

6 **E. The Generic Computer Elements Do Not Transform the Asserted**
 7 **Claims Into Claims Eligible for Patent Protection**

8 During prosecution, Hemopet overcame a 35 U.S.C. § 101 rejection by reciting
 9 a generic computer and algorithm in the claims. (Ex. 16, ‘343 Pros. History, 4/13/10
 10 Amendment at 16). However, since the Asserted Claims were issued, the Supreme
 11 Court has made clear that “the mere recitation of a generic computer cannot transform
 12 a patent-ineligible abstract idea into a patent-eligible invention.” *Alice*, 134 S.Ct. at
 13 2358. “Stating an abstract idea while adding the words ‘apply it with a computer’
 14 simply combines those two steps, with the same deficient result.” *Id.* (internal citation
 15 omitted). The specific claim limitations “a computer,” “at least one electronic
 16 database coupled to the computing system,” and “at least one software routine
 17 executing on the computer system” are “purely functional and generic.” *Id.* at 2360.
 18 Nearly every computer includes “at least one electronic database coupled to the
 19 computing system” and “at least one software routine executing on the computing
 20 system.” *Id.* As a result, none of the hardware recited by the system claims offers a
 21 meaningful limitation beyond generally linking the use of the method to a particular
 22 technological environment, that is, implementation via computer. *Id.* As in *Alice*, the
 23 claims here recite no more than a generic computer, generic software or generic
 24 algorithm, or generic computer database. These elements cannot transform the
 25 ineligible matter any more than they could in *Alice*.

26 Additionally, it does not matter if the volume of data is large and labeled
 27
 28

1 “genomic.”³ During prosecution, in response to the same lack of enablement
 2 rejection mentioned above, Hemopet also submitted a declaration from James Spencer
 3 declaring “data is data” and “the analysis, selection, design and development of
 4 nutrition would have relatively been quickly apparent after the different data were
 5 uploaded and processed.” (Ex. 17, Spencer Decl. at ¶¶ 9, 7). “Even though the
 6 volume of data may be large, or because the data may be labeled as ‘genetic,’
 7 ‘genomic’ or medical or diagnostic data does not mean that the analysis is complex to
 8 a person regularly skilled in data analysis, nor would it have been complex in 1999.”
 9 (*Id.* at ¶ 11). Hemopet cannot save the claims by contradicting the positions it took
 10 during prosecution.

11 **F. Hemopet Seeks To Pre-empt the Field of Nutrigenomics**

12 In addition to the prescribed analysis above, the Supreme Court also requires
 13 analyzing whether the Asserted Claims improperly attempt to pre-empt an entire field.
 14 As such, when “examining whether a claim is patent eligible under Section 101, a
 15 court should consider whether the claim poses a risk of pre-empting the law of nature
 16 contained in the claim.” *Genetic*, 2014 WL 4379587 at *14; *see also Alice*, 134 S. Ct.
 17 at 2354. Hemopet admits that it is seeking to pre-empt the use of nutrigenomics in
 18 determining nutritional diets for pets: its inventor Dr. Dodds asserts, “I have secured
 19 the pioneer patents for nutrigenomics pet foods dating back to 1999. These are
 20 patents 7,865,343 and 8,060,354 … [a]s a result, I am effectively the gatekeeper to a
 21 concept…” (Ex. 14, HEMOPET0005705). According to Dr. Dodds, anyone who

22
 23 3 Hemopet admits that even a handful of genes could be genomic in scale. (Ex. 12,
 24 Sutter Dep. at 169:15-23). As such, it is irrelevant that the claimed methods might
 25 include an example where thousands of genes are analyzed. *See Planet Bingo,*
LLC v. VKGS LLC, No. 2013-1663, 2014 WL 4195188, *2 (Fed. Cir. 2014, Aug.
 26, 2014) (“We need not, and do not, address whether a claimed invention
 27 requiring many transactions might tip the scales of patent eligibility, as the claims
 fall far short of capturing an invention that necessarily handles ‘thousands, if not
 millions’ of bingo numbers of players.”).

1 wants to practice nutrigenomics with respect to canines and felines must follow the
 2 claimed process. (*Id.*) As applied by Hemopet, the Asserted Claims pre-empt the
 3 entire use of nutrigenomics to determine a particular nutrient or caloric composition
 4 for a canine or feline.⁴ Such pre-emption is not allowed. *Alice*, 134 S.Ct. at 2354.

5 **III. THE ASSERTED CLAIMS OF THE ‘354, ‘587, AND ‘099 PATENTS
 6 ARE INVALID AS ANTICIPATED BY PCT GHAI**

7 **A. Summary Judgment of Anticipation Is Appropriate**

8 Summary judgment of anticipation is appropriate when the record reveals no
 9 genuine dispute as to whether the prior art reference discloses all the claimed
 10 elements. *Leggett & Platt, Inc. v. VUTEK, Inc.*, 537 F.3d 1349, 1352, 1356 (Fed. Cir.
 11 2008); *see also Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327
 12 (Fed. Cir. 2001). Although the defendant has the burden to establish anticipation by
 13 clear and convincing evidence, summary judgment is nonetheless appropriate when no
 14 genuine issue of fact exists. *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d
 15 955, 962 (Fed. Cir. 2001); *see also SmithKline Beecham Corp v. Apotex Corp.*, 403
 16 F.3d 1331, 1344 (Fed. Cir. 2005).

17 An anticipation analysis involves two steps: (1) the Court construes the claims
 18 and (2) the properly-construed claims are compared to the prior art. *Helifix Ltd. v.
 19 Blok-Lok, Ltd.*, 208 F.3d 1339, 1346-47 (Fed. Cir. 2000). The prior art anticipates a
 20 claim “if each and every limitation is found either expressly or inherently in a single
 21 prior art reference.” *King Pharms., Inc. v. Eon Labs., Inc.*, 616 F.3d 1267, 1274 (Fed.
 22 Cir. 2010). A prior art reference inherently discloses a claim element if the feature is
 23 “necessarily present” in that single anticipating reference. *SmithKline Beecham*, F.3d
 24

25

 26 ⁴ The fact that Hemopet seeks to pre-empt the use of nutrigenomics only for pets
 27 does not save the Asserted Claims. *Alice*, 134 S.Ct. at 2358 (“the prohibition
 against patenting abstract ideas cannot be circumvented by attempting to limit the
 use of [the idea] to a particular technological environment”) (citation omitted).

1 1331 at 1343; *see also Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373,
 2 1377 (Fed. Cir. 2003) (district court properly granted summary judgment of
 3 anticipation based on prior art inherently disclosing claim element).

4 **B. PCT Ghai Is Prior Art to the ‘354, ‘587, and ‘099 Patents**

5 PCT Ghai was filed on June 20, 1996, and published on December 24, 1997.
 6 (Ex. 5, PCT Ghai at Cover). PCT Ghai is prior art to the ‘354, ‘587, and ‘099 Patents
 7 under 35 U.S.C. §102(b) because it was publicly available more than one year prior to
 8 the alleged earliest filing date of the Asserted Patents, October 1999. Hemopet does
 9 not dispute that PCT Ghai is prior art to the Asserted Claims. And there is no dispute
 10 that PCT Ghai was not before the PTO, and the PTO examiner was unable to consider
 11 PCT Ghai when examining the patents.

12 **C. PCT Ghai Discloses Each Element of the Asserted Claims of the ‘354,
 13 ‘587, and ‘099 Patents**

14 Hemopet does not dispute that PCT Ghai discloses the claim limitations of the
 15 ‘354, ‘587, and ‘099 Patents except the presence of a computer, computer software or
 16 databases. The narrow dispute before the Court is whether PCT Ghai *inherently*
 17 discloses those computer elements that Hemopet contends are not expressly present.

18 **1. Hemopet Asserts Only That PCT Ghai Fails To Disclose The
 19 Computer-Related Limitations of the Asserted Claims**

20 Hill’s expert, Dr. Jean Hall, explained that PCT Ghai discloses each and every
 21 limitation of the asserted claims of the ‘354, ‘587, and ‘099 Patents. (Ex. A to Hall
 22 Decl. at ¶¶62-67, Exhibit F). Hemopet’s expert, Dr. Nate Sutter, provided a five-
 23 paragraph response to Hill’s contention that PCT Ghai anticipates the ‘354, ‘587, and
 24
 25
 26
 27
 28

1 ‘099 Patents. (Ex. 7, 7/17/14 Sutter Report at ¶¶150-155).⁵ Dr. Sutter opines that
 2 PCT Ghai does not disclose the computer related elements, *i.e.*, a computer or
 3 software routines (¶151), a computer (¶152), software routines executing on a
 4 computing system (¶154), or using a suitably programmed computer or having a
 5 computer-readable medium or a software routine (¶155). (Ex. 7, 7/17/14 Sutter at
 6 ¶¶150-155; Ex. 12, Sutter Dep. at 180:11-14, 180:23-181:10, 184:4-7, 184:23-185:7,
 7 185:14-21). Dr. Sutter does not dispute that PCT Ghai discloses the steps of the
 8 claimed methods or that it discloses the claimed functionality of the systems; rather,
 9 he disputes that PCT Ghai discloses *using a computer or software routines* to carry
 10 out the functions. (See Ex. 7, 7/17/14 Sutter Report at ¶¶150-155). Thus, for the
 11 ‘354, ‘587, and ‘099 Patents, Dr. Sutter does not dispute that PCT Ghai discloses
 12 every claim element except for the presence of a computer. (Ex. 7, 7/17/14 Sutter at
 13 ¶¶150, 151, 152, 154, and 155; Ex. 12, Sutter Dep. at 185:14-21).

14 **2. PCT Ghai Inherently Discloses The Computer Elements**

15 PCT Ghai discloses that “the expression levels of a large number of messenger
 16 RNAs can be simultaneously measured by the high throughput hybridization assays
 17 based on DNA arrays or DNA ***microarrays***.” (Ex. 5, PCT Ghai at 8:22-34).
 18 Hemopet’s expert, Dr. Sutter admitted that the express disclosure of microarray
 19 experiments inherently discloses, indeed necessarily requires, a computer, software
 20 and database be used:

21 Q. ***So in the context of a microarray experiment*** based on the volume
 22 of information that a microarray requires, ***we're necessarily***

23
 24 5 In paragraph 153, Dr. Sutter provides an additional alleged distinction over PCT
 25 Ghai, but it is applicable only to the ‘343 Patent. (Ex. 7, 7/17/14 Sutter Report at
 26 ¶153; Ex. 12, Sutter Dep. at 183:4-184:2). Though Hill’s disagrees with Dr. Sutter,
 27 because he raised an additional technical distinction regarding the ‘343 Patent, to
 streamline this motion Hill’s does not seek summary judgment of anticipation
 regarding the ‘343 Patent, and will present that at trial.

talking about requiring a computer to store and analyze that data; correct?

A. Yes.

(Ex. 12, Sutter Dep. at 75:22-76:2) (emphasis added). Dr. Sutter further confirmed that microarray experiments involve the use of databases and software routines. (*Id.* at 74:1-15, 74:25-75:7). PCT Ghai’s disclosure of microarray experiments confirms that PCT Ghai inherently discloses the computer, database, and software elements of the asserted claims of the ‘354, ‘587, and ‘099 Patents. PCT Ghai thus inherently anticipates these claims. *Schering Corp.*, 339 F.3d at 1377 (“[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.”). Accordingly, there is no genuine issue of material fact that PCT Ghai discloses all the claim elements and anticipates the asserted claims of the ‘354, ‘587, and ‘099 Patents. Accordingly, this Court should grant summary judgment that PCT Ghai anticipates the Asserted Claims of the ‘354, ‘587, and ‘099 Patents.

IV. HILL'S DOES NOT INFRINGE THE ASSERTED PATENTS BECAUSE THE RDD PROGRAM DOES NOT INCLUDE THE CLAIMED SECOND DATA

Hill’s non-infringement motion turns on one question—whether Hill’s RDD program’s use of mRNA data satisfies the “second data” claim element in light of the Court’s claim construction that includes “gene product.” Given the Court’s construction and the patentee’s express definition of the term “gene product,” the answer is no.

A. Summary Judgment of Non-infringement Is Appropriate

A literal infringement analysis requires two steps.⁶ First, the court interprets the claims as a matter of law to determine their meaning and scope. *Southwall*

⁶ Hemopet does not assert infringement under the doctrine of equivalents.

1 *Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). Second,
 2 the trier of fact determines whether the claims as construed read on the accused
 3 product. *Id.* “To establish literal infringement, every limitation set forth in a claim
 4 must be found in an accused product, exactly.” *Id.*

5 **B. The Court’s Construction of “Expression Of” Requires that the
 6 Claimed “Second Data” Be Phenotypic Data**

7 Each Asserted Claim includes the limitation “expression of.” Claim 1 of the
 8 ‘343 Patent claims “second data comprising the effect of nutrition on the *expression*
 9 *of* the genetic descriptor genomic data.” (Ex. 1 at claim 1). Claims 1, 2, 9 and 10 of
 10 the ‘354 Patent and Claims 1 and 8 of the ‘587 Patent claim “second data comprising
 11 the effect of nutrition on the *expression of* at least one gene in/of/from the genomic
 12 map.” (Exs. 3-4). Claim 1 of the ‘099 Patent claims “second data comprising the
 13 effect of nutrition on the *expression of* genes in the genomic map.” (Ex. 3 at claim 1).

14 Adopting Hemopet’s proposed construction, the Court construed “expression
 15 *of*” to mean “the level of gene product.” (D.I. 76 at 14). The Court noted in its claim
 16 construction order that the specification in each of the Asserted Patents defined gene
 17 product: “[i]n this application, the term ‘gene product’ means the specific phenotypic
 18 characteristic(s) resulting from the expression of the genotype, and may contain
 19 certain laboratory test data.” (*Id.* at 13-14). As such, to satisfy the “expression of”
 20 limitations in the second step of the infringement analysis requires that the accused
 21 program include the specific phenotypic characteristic(s) data resulting from the
 22 expression of the genotype.

23 As discussed below, phenotypic and genotypic characteristics are different.
 24 mRNA is a genotypic characteristic. Because the accused RDD program only uses
 25 mRNA data, it does not infringe the Asserted Claims.

26 **C. mRNA Data Is Not Phenotypic Data**

27 The distinction between phenotype and genotype is fundamental and well

1 known in the art. A biology text book describes “phenotype” as “[a]n individual’s
 2 observable traits.” (Ex. 21, Biological Science, 5th Edition at 258; Ex. B to Hall Decl.
 3 at ¶184). It further provides that “[b]iologists refer to the observable traits of an
 4 individual, such as the shape of a pea seed or the eye color of a person, as its
 5 phenotype (literally, ‘show-type’).” (*Id.* at 258, Paragraph 2; Ex. B to Hall Decl. at
 6 ¶184). “Genotype,” on the other hand, is described as “[t]he alleles [different versions
 7 of the same gene are called alleles] found in a particular individual.” (*Id.* at 261,
 8 Paragraphs 5-6; Ex. B to Hall Decl. at ¶184). U.S. Pat. Nos. 6,287,254 (“the ‘254
 9 patent”) and 6,730,023 (“the ‘023 patent”), incorporated by reference in the Asserted
 10 Patents, confirm the point:

11 “The physical attributes, and other descriptive and health assessment
 12 information is generally termed in this application as the phenotypic
 13 information. Genetic disorder information is termed in this application as
 14 the genotypic information. Generally, these are two distinct and differing
 sets of information.”

15 (Ex. 19, ‘254 patent at 1:44-49; Ex. 20, ‘023 patent at 1:35-40).

16 Dispositive on the issue before the Court, mRNA and RNA expression are
 17 genotypic information, not phenotypic. Hemopet’s expert Dr. Sutter admitted that
 18 “***RNA expression [mRNA] is one example of information related to the organism’s***
 19 ***genotype as contemplated by the patent.***” (Ex. 6, 6/19/14 Sutter Report at ¶ 83)
 20 (emphasis added).

21 **D. The Accused Second Data in the RDD Program Is mRNA Data, Not**
 22 **Phenotypic Data**

23 Hemopet asserts that Hill’s satisfies the second data element in two ways. First,
 24 Hemopet contends that “[t]he results of Hill’s testing of various ingredients and
 nutrients *in vitro* constitutes the claim [sic] second data.” (*Id.* at ¶86). Second,
 25 Hemopet contends that “[t]he results of Hill’s *in vivo* testing fall within the scope of
 26 the claimed ‘second data.’” (*Id.* at ¶ 88). However, both Hill’s *in vitro* and *in vivo*
 27 tests measure mRNA levels, which by Hemopet’s own admission is genotypic, not
 28

1 phenotypic data, and thus outside the scope of the construed claims.

2 **1. Hill's *in vitro* ingredient studies measure mRNA**

3 Gene expression as measured by mRNA is the only response measured and
 4 collected during Hill's *in vitro* ingredient cell culture studies. (See, e.g., Ex. 9, D.
 5 Jewell Dep. at 25:9-18, 31:15-20, 33:25-34:2; Ex. B to Hall Decl. at ¶¶65-67, 73-74,
 6 77). Neither phenotypic characteristics nor phenotypic measurements are determined
 7 or collected as part of the *in vitro* ingredient cell culture studies. (*Id.*)

8 Hill's conducts the *in vitro* ingredient studies using cell lines. (Ex. 9, D. Jewell
 9 Dep. at 26:2-17). Hill's ingredient studies evaluate the effect of an individual
 10 ingredient extract on cell lines as measured by the change in mRNA levels of the cell
 11 lines. (Ex. 9, D. Jewell Dep. at 25:9-18, 28:1-23, 31:15-20, 33:25-34:2).

12 To analyze the ingredient's effect on the cell lines, Hill's uses Affymetrix
 13 GeneChips to measure the intensity of mRNA present in both samples (treated and
 14 non-treated samples). (Ex. 9, D. Jewell Dep. at 31:15-20, 33:25-34:2; Ex. 8, S.
 15 Malladi Dep. at 20:6-21:3). No phenotypic characteristics data are measured in
 16 connection with the ingredient cell culture tests. (Ex. 9, D. Jewell Dep. at 25:9-18,
 17 28:1-23; 31:15-20, 33:25-34:2; Ex. B to Hall Decl. at ¶¶65-67, 73-74, 77).

18 **2. Hill's *in vivo* ingredient studies measure mRNA**

19 Hill's performs feeding studies where it feeds prototype investigational diets to
 20 populations of animals, and conducts tests to assess the efficacy of those diets. (Ex. 9,
 21 D. Jewell Dep. at 61:4-62:1, 62:21-63:10). Hill's *in vivo* feeding studies measure the
 22 gene expression profiles of animals. (*Id.*) The gene expression measurements
 23 collected from the *in vivo* feeding tests consist of mRNA levels (*i.e.*, gene expression
 24 data). (Ex. 9, D. Jewell Dep. at 61:4-62:1, 62:21-63:10; *see also* Ex. B to Hall Decl.
 25 at ¶¶98-100). No phenotypic characteristics data are measured as part of the gene
 26 expression analysis. (*Id.*)

27 Accordingly, this Court should grant summary judgment that Hill's does not
 28

1 infringe the Asserted Claims as the Hill's program lacks the required second data.

2 **V. PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT IS**
 3 **WARRANTED**

4 In order to avoid confusion at trial and streamline the issues, Hill's requested
 5 that Hemopet stipulate that: (1) Hill's acts of using, selling, or offering for sale pet
 6 food products do not infringe the Asserted Claims; (2) the process that Hill's uses to
 7 manufacture pet food products does not infringe the Asserted Claims; and (3) Hill's
 8 identification of key ingredients prior to the issuance of the Asserted Patents does not
 9 infringe the Asserted Claims. Hemopet refused to agree to any of the stipulations,
 10 seemingly to maintain a damages theory based on Hill's pet food products.

11 **A. Hill's Pet Food Products Do Not Infringe**

12 The act of using, selling, or offering for sale Hill's accused pet food products
 13 does not infringe the Asserted Claims.

14 This is plain on a review of the Asserted Claims, which are directed to
 15 determining and preparing a dog or cat food recipe—not the use or sale of pet food
 16 products. For example, the claimed systems and methods require analyzing data using
 17 a computer—there can be no dispute that a bag of pet food does not include a
 18 computer, or the first or second data as required by each of the Asserted Claims. (*See,*
 19 *e.g.*, Ex. 1 at claim 1). Moreover, when asked, Hemopet's expert admitted that pet
 20 food does not infringe the Asserted Claims:

21 Q Does Hill's act of selling or offering for sale pet food in the
 22 marketplace infringe any of the asserted claims?

23 A The act of selling dog or pet food in the marketplace considered in
 24 a vacuum without a context of where the bag came from, how it
 25 got to have nutrient composition in the bag, the act of selling the
 26 bag at Petsmart, money changes hands, is not an act that I read is
 27 disclosed in the claim language. That act considered in vacuum
 28 without a -- without a broader context is not an infringing
 act, in my opinion.

1 (Ex. 12, Sutter Dep. at 100:23-101:9; *see also id.* at 100:14-19). By Hemopet's own
 2 admissions, there is no dispute that Hill's pet food products do not infringe.

3 However, notwithstanding that admission, Dr. Sutter's expert report states that
 4 "Hill's infringes ... by making, using, selling, or offering for sale certain products
 5 developed through the use of Hill's RDD process." (Ex. 6, 6/19/14 Sutter Report at
 6 ¶17). That statement, Dr. Sutter's resistance to agreeing to this point at his deposition,
 7 and Hemopet's refusal to stipulate require summary judgment to avoid jury confusion
 8 and streamline the trial. Thus, Hill's moves for summary judgment that the act of
 9 using, selling, or offering for sale Hill's pet food does not infringe.

10 **B. Manufacturing Pet Food Does Not Infringe the Asserted Claims**

11 Hill's also asked Hemopet to stipulate that Hill's process of manufacturing pet
 12 food does not infringe any of the Asserted Claims. The Asserted Claims recite
 13 elements specific to the creation of a formula or composition (*i.e.*, a recipe) for a pet
 14 food, as distinguished from—*after* a recipe exists—gathering the ingredients and
 15 manufacturing the actual food. Hemopet cannot dispute that its Asserted Claims do
 16 not cover that manufacturing process. The Asserted Claims include a number of
 17 limitations that Hill's manufacturing process does not do, for example, comparing the
 18 first and second data to identify the potential nutrients or caloric compositions for dog
 19 and cat food. Indeed, the Court recognized during the claim construction process that
 20 the Asserted Claims are not directed to manufacturing pet foods: "[m]anufacture' has
 21 an association with large-scale, routine, industrial production, which is inconsistent
 22 with the individualized assessments of particular canines and felines contemplated by
 23 the patents at issue." (D.I. 76 at 16). Hemopet did not even attempt to show that
 24 Hill's pet food manufacturing process infringed. Thus, summary judgment that Hill's
 25 process of manufacturing pet food does not infringe is appropriate.

C. Hill's Pre-Patent Identification of The Key Ingredients Does Not Infringe

Hill’s used RDD to identify the key ingredients in the Accused Products by 2009—approximately two years before the first Asserted Patent issued. Infringement cannot be based on activities that occur before the issuance of a patent. *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1360 (Fed. Cir. 2007) (summary judgment of no infringement when steps of claimed method were performed prior to issuance).

It is undisputed that Hill's used RDD—in 2009—to identify three key ingredients—tomato pomace, carrot powder, and coconut oil—in Hill's accused Metabolic pet food. Hill's established the Global Nutritional Standard for Metabolic—including those ingredients—*before* any of the Asserted Patents issued. (Ex. 10, K. Hahn Dep. at 97:1-9, 96:17-22, 106:4-21). Based on those pre-issuance formula guidelines, Hill's then used the tomato pomace, carrot powder, and coconut oil as key ingredients in four other products associated with Hemopet's infringement claims, Hill's Science Diet Perfect Weight, Ideal Balance Slim & Healthy, Science Plan VetEssentials Neutered Dog, and the proposed multisystem pet food. (Ex. 10, K. Hahn Dep. at 106:4-21, 108:5-12). As in *Monsanto*, Hill's pre-issuance RDD use to identify the three key ingredients cannot infringe. *Monsanto*, 503 F.3d at 1360 (“statute does not reach pre-issuance use of the later-patented process”).

VI. CONCLUSION

For the foregoing reasons, Hill's respectfully requests that the Court GRANT its Motion for Summary Judgment of Patent Invalidity under 35 U.S.C. §§ 101, 102 and Non-Infringement, as set forth herein.

1 Respectfully submitted,

2 DATED: September 18, 2014

KIRKLAND & ELLIS LLP

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CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2014, I electronically filed the foregoing document with the Clerk of Court using CM/ECF, which sent notification of such filing to all counsel of record.

/s/ *Bryan S. Hales*

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION**

HEMOPET,

Plaintiff,

V.

HILL'S PET NUTRITION, INC.

Defendant.

JURY TRIAL DEMANDED

Case No. SACV 12-01908-(JLS-JPRx)
Action Filed: November 2, 2012

**[PROPOSED] ORDER GRANTING
HILL'S MOTION FOR SUMMARY
JUDGMENT OF PATENT
INVALIDITY UNDER 35 U.S.C. §§ 101,
102 AND NON-INFRINGEMENT**

DATE: November 14, 2014

TIME: 2:30 p.m.

COURTROOM: 10-A

JUDGE: The Honorable Josephine Staton

Defendant Hill's Pet Nutrition, Inc.'s ("Hill's") Motion for SUMMARY JUDGMENT OF PATENT INVALIDITY UNDER 35 U.S.C. §§ 101, 102, and NON-INFRINGEMENT came on for hearing this date, all counsel duly appearing.

After considering the moving and opposition papers, all evidence submitted in support thereof, the arguments of counsel, both written and oral, and all other matters presented to the Court.

IT IS HEREBY ORDERED THAT Hill's Motion for Summary Judgment Of Patent Invalidity Under 35 U.S.C. §§ 101, 102, and Non-Infringement is GRANTED.

Dated:

By: _____
Honorable Josephine L. Staton
United States District Court Judge